UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION

RONNIE MORGAN,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 3:15-CV-32
	§	
MEDTRONIC, INC,	§	
	§	
Defendant.	§	

MEMORANDUM OPINION AND ORDER

Pending before the Court is Defendant Medtronic, Inc.'s ("Medtronic"), Motion for Judgment on the Pleadings ("12(c) Motion") pursuant to Rule 12(c) of the Federal Rules of Civil Procedure (Dkt. 5). For the reasons explained below, the Court finds that Medtronic's 12(c) Motion should be **GRANTED** in its entirety. Accordingly, Plaintiff Ronnie Morgan's ("Morgan") claims are **DISMISSED WITH PREJUDICE**.

FACTUAL BACKGROUND

In this products liability lawsuit, Morgan asserts Texas state-law claims for negligence, strict liability, and breach of warranties against Medtronic.[1] *See* Original Petition ("Or. Pet."), Dkt. # 1-1 at 4-14.[3] Morgan alleges that the SynchroMed II Implantable Infusion System (the "SynchroMed II Pump") was surgically implanted beneath his skin to deliver medication (*i.e.*, morphine sulfate or baclofen).

[1] In his original claim, Morgan sued Medtronic PS Medical, Inc. However, Medtronic states that Medtronic PS Medical, Inc. does not manufacture or sell the device by which the Morgan alleges he was injured, the SynchroMed II Pump. Medtronic, Inc.—not Medtronic PS Medical, Inc.—sells the SynchroMed II Pump. Morgan does not submit any facts to allege the contrary nor does the record indicate otherwise.

Morgan alleges that, sometime before October 2013, a SynchroMed II Pump was implanted to address his chronic pain. Or. Pet., Dkt. 1-1, ¶ 6. Morgan was admitted to Clear Lake Regional Medical Center with symptoms consistent with drug withdrawal. *Id.* at ¶ 7. Morgan alleges that his pump malfunctioned by failing to provide a warning "that the pump no longer had morphine in it," and as a result, "[Morgan] unknowingly went through morphine withdrawal symptoms." *Id.* at ¶¶ 8-9. A week later, Morgan's SynchroMed II Pump was removed and replaced. *Id.* at ¶ 10. Morgan contends that he suffered "permanent injuries and damages" as a result of these events. *Id.* at ¶ 11.

PROCEDURAL BACKGROUND

Morgan filed suit in state court on January 15, 2015, asserting seven state-law causes of action: (1) negligence (Or. Pet., Dkt. 1-1, ¶¶ 12-17); (2) "strict product liability – design defect" (*id.* at ¶¶ 18-23); (3) "strict product liability – failure to warn" (*id.* at ¶¶ 24-29); (4) "strict products liability – manufacturing defect" (*id.* at ¶¶ 30-34); (5) breach of express warranty (*id.* at ¶¶ 35-39); (6) breach of implied warranty of merchantability (*id.* at ¶¶ 40-45); and (7) breach of implied warranty of fitness for a particular purpose (*id.* at ¶¶ 46-51). Medtronic answered in state court, raising various affirmative defenses (including the defense of federal preemption), and then removed the case to this Court. *See* Dkt. 1; Original Answer, Dkt. 1-1 at 19-30.

Medtronic has filed a 12(c) Motion arguing that because the SynchroMed II Pump is a Class III PMA device and the affirmative defense of federal preemption is purely a legal matter that can be decided on the pleadings. *See* 21 U.S.C. §§ 360k(a), 337(a). Additionally, Medtronic argues that Morgan's failure to provide pre-suit notice to

Medtronic as required by TEX. BUS. & COM. CODE § 2.607(c)(1) bars his warranty claims as a matter of law. For the reasons detailed below, the Court agrees.

MOTION FOR JUDGMENT ON THE PLEADINGS

A motion brought pursuant to Federal Rule of Civil Procedure 12(c) should be granted if there is no issue of material fact and if the pleadings show that the moving party is entitled to judgment as a matter of law. *Greenberg v. General Mills Fun Group*, Inc., 478 F.2d 254, 256 (5th Cir. 1973). A motion for judgment on the pleadings is subject to the same standard as a motion to dismiss for failure to state a claim. *See In re Great Lakes Dredge & Dock Co. LLC*, 624 F.3d 201, 209 (5th Cir. 2010); *Guidry v. American Public Life Insurance Co.*, 512 F.3d 177, 180 (5th Cir. 2007); *Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir. 1999) (per curiam).

The Court must accept the factual allegations of the complaint as true, view them in a light most favorable to the plaintiffs, and draw all reasonable inferences in the plaintiffs' favor. *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). "When a federal court reviews the sufficiency of a complaint, before the reception of any evidence either by affidavit or admissions, its task is necessarily a limited one. The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 122 S.Ct. 992, 997, 152 L.Ed.2d 1 (2002).

To avoid dismissal, a plaintiff must allege "'enough facts to state a claim to relief that is plausible on its face.'" *Doe v. MySpace, Inc.*, 528 F.3d 413, 418 (5th Cir. 2008) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1974, 167

L.Ed.2d 929 (2007)). Plausibility requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (quoting *Twombly*, 127 S.Ct. at 1966) (internal quotation marks omitted). The court will "not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010). "[D]ismissal is proper if the complaint lacks an allegation regarding a required element necessary to obtain relief." *Torch Liquidating Trust ex rel. Bridge Assocs. L.L.C. v. Stockstill*, 561 F.3d 377, 384 (5th Cir. 2009).

When considering a motion to dismiss, courts are generally "limited to the complaint, any documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint." *Lone Star Fund V (U.S.), L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010) (citing *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498–99 (5th Cir. 2000)); *see also C.H., II ex rel. L.H. v. Rankin Cnty. Sch. Dist.*, 415 Fed. Appx. 541, 545 (5th Cir. 2011) ("A district court may look to the pleadings and any documents attached thereto."); *cf. Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 313 (5th Cir.2002) (surveying the Fifth Circuit's jurisprudence regarding "the documents that a district court may properly consider in deciding a Rule 12(c) motion").

In addition, the court may take judicial notice of matters of public record, including pleadings filed in state court. *See Joseph v. Bach & Wasserman, L.L.C.*, 487 Fed. App'x. 173, 178 (5th Cir. 2012) ("[T]he court may take judicial notice of matters of public record. Here, the document referenced is a pleading filed with a Louisiana state district court, and it is a matter of public record." (citation omitted) (citing *Funk v. Stryker Corp.*, 631 F.3d 777 (5th Cir. 2011))); *Norris v. Hearst Trust*, 500 F.3d 454, 461 n. 9 (5th Cir. 2007) ("[I]t is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record."); *Hebert Abstract Co., Inc. v. Touchstone Properties, Ltd.*, 914 F.2d 74, 76 (5th Cir. 1990) ("A motion brought pursuant to FED .R. CIV. P. 12(c) is designed to dispose of cases where the material facts are not in dispute and a judgment on the merits can be rendered by looking to the substance of the pleadings and any judicially noticed facts.").

When a party presents "matters outside the pleadings" with a motion to dismiss, the court has discretion to either accept or exclude the evidence for purposes of the motion to dismiss. *See McBurney v. Cuccinelli*, 616 F.3d 393, 410 (4th Cir. 2010) ("'As is true of practice under Rule 12(b)(6), it is well-settled that it is within the district court's discretion whether to accept extra-pleading matter on a motion for judgment on the pleadings and treat it as one for summary judgment or to reject it and maintain the character of the motion as one under Rule 12(c).'" (quoting 5C Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1371 (3d ed. 2010))); *Isquith ex rel. Isquith v. Middle South Utilities, Inc.*, 847 F.2d 186, 194 n.3 (5th Cir. 1988) ("Rule 12(b) gives a district court 'complete discretion to determine whether or not to accept any

material beyond the pleadings that is offered in conjunction with a Rule 12(b)(6) motion.'" (quoting 5C Charles A Wright & Arthur R. Miller, Federal Practice and Procedure § 1366 (1969))). However, "[i]f ... matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56" and "[a]ll parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." FED. R. CIV. P. 12(d).

Attached to Medtronic's 12(c) Motion are: (1) the SynchroMed II Programmable Drug Infusion System Premarket Approval Database Listing for P860004/S056 (Dkt. 5, Exhibit A), and (2) the SynchroMed Premarket Approval Database Listing (Dkt. 5, Exhibit B). Because these documents are matters of public record of which the Court may take judicial notice, the Court will consider these documents without converting the 12(c) Motion to a motion for summary judgment. *See Van Duzer v. U.S. Bank Nat. Ass'n*, 995 F. Supp. 2d 673, 683-85 (S.D. Tex.) *aff'd*, 582 F. App'x 279 (5th Cir. 2014). These documents are also referenced in Morgan's Original Complaint, and they are central to his claims because they show that the SynchroMed II Pump is a Class III, PMA approved medical device.

ANALYSIS

Medtronic argues that the Food and Drug Administration ("FDA") approved the SynchroMed II Pump under its Premarket Approval ("PMA") process and that Morgan's claims should be dismissed because they are (1) expressly preempted under 21 U.S.C. § 360k(a) (to the extent they are based on state-law) and (2) impliedly preempted under 21 U.S.C. § 337(a) (to the extent they are attempting to enforce federal law regarding the

SynchroMed II Pump). *See* Dkt. 5. Additionally, Medtronic argues that Morgan's breach-of-warranty claims are barred by his noncompliance with the pre-suit notice requirements contained in TEX. BUS. & COM. CODE § 2.607(c)(1). *Id.*

Morgan responds that Medtronic's 12(c) Motion is premature because the pleadings are not yet closed. Dkt. 8, ¶ 6. Morgan contends that this case was initially filed in state court, so he was only required to give Medtronic notice of his claim. *Id.* at ¶ 10. Finally, Morgan states that in order to prove his claims, discovery must take place and that he has alleged enough facts to prove each element of a product liability claim for a manufacturing defect. *Id.* at ¶¶ 11, 12.

A. Medical Device Amendments

The Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA")[2] were promulgated in 1976 as a response to increasing state regulation of medical devices in the wake of the failure of the Dalkon Shield contraceptive device. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). The MDA[3] brings the regulation of medical devices under the purview of the U.S. Food and Drug Administration ("FDA") and establishes three (3) classes of medical devices and corresponding regulatory requirements. *Riegel*, 552 U.S. at 316–17. Congress enacted the MDA in 1976 and granted the FDA authority to regulate the safety and effectiveness of medical devices sold in the United States. 21 U.S.C. §§ 301 *et seq.* Under the MDA,

[2] 31 U.S.C. § 301, *et seq.*
[3] 21 U.S.C. § 360c, *et seq.*

different types of medical devices receive different levels of scrutiny. *Riegel*, 552 U.S. at 316–17.

The devices receiving the most scrutiny are those in Class III, which includes Morgan's SynchroMed II Pump.[4] A Class III device is subject to a rigorous premarket approval process that includes FDA review of the device's benefits, effectiveness, risks of injury, and proposed labeling. 21 U.S.C. § 360c(a)(1)(C). After receiving approval, a manufacturer must receive supplemental approval from the FDA before making any changes to the device that affect safety or effectiveness. *Id.* at § 360e(d)(6)(A)(i).

B. Federal Preemption

To preserve the FDA's regulatory authority over medical devices, the MDA includes an express preemption provision that provides, with a few exceptions not applicable here, that:

> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.[5]

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[4] The Court takes judicial notice of FDA websites verifying that the SynchroMed II Pump at issue in this case is a Class III, PMA approved medical device. Dkt. 1-1, ¶ 6; *see also* SynchroMed II Programmable Drug Infusion System Premarket Approval Database Listing for P860004/S056. Dkt. 5, Exhibit A. There is no opposition and no argument from Morgan that the device at issue is not so classified. The Court may take judicial notice of the FDA's PMA documents because they are public government records that are not subject to reasonable dispute. FED. R. EVID. 201(b); *see, e.g., Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011) ("[W]e hold that it was appropriate for the [district] court to take judicial notice, under Rule 12(b)(6), of the PMA the FDA granted to Stryker for marketing its [medical device]."); *McBride v. Medtronic, Inc.*, No. 13-377, 2013 WL 3491085, at *2 (W.D. La. July 10, 2013) ("[W]e hereby take judicial notice of the FDA information presented by Medtronic verifying that the Synchro[M]ed II [P]ump is a Class III PMA device.").

[5] 21 U.S.C. § 360k (a).

The Supreme Court discussed this provision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), and established a two-step analysis for determining whether a state-law claim is expressly preempted. First, the court must determine whether the federal government established requirements applicable to the medical device. *Id.* at 321–23. Second, the court must determine whether the state-law claim would impose requirements "different from, or in addition to," the federal requirements. *Id.* A state-law claim is expressly preempted if the answer to both questions is "yes." This is known as "express preemption," because it is based on the express language of the statute.

A state-law claim escapes express preemption if the claim imposes duties that parallel the federal requirements because the second step of the *Riegel* analysis is not satisfied. But such a claim may nonetheless be impliedly preempted under 21 U.S.C. § 337(a). The Supreme Court discussed implied preemption in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and noted that the MDA provides that all actions to enforce FDA requirements " 'shall be by and in the name of the United States.' " *Id.* at 349 n. 4 (quoting 21 U.S.C. § 337(a)). The Supreme Court concluded that a parallel state-law claim is impliedly preempted where it "exist[s] solely by virtue" of the federal requirements. *Id.* at 353. Courts have applied express and implied preemption in dismissing claims similar to Morgan's brought against other medical device manufacturers—often at the pleading stage.[6]

[6] *See, e.g., Rodriguez v. Am. Med. Sys., Inc.*, 597 F. App'x 226, 227 (5th Cir. 2014) (affirming summary judgment on strict-liability and DTPA claims based on express preemption); *Funk v. Stryker Corp.*, 631 F.3d 777, 781-82 (5th Cir. 2011) (affirming Rule 12(b)(6) dismissal, on express preemption grounds, of strict-liability, negligence, and statutory claims brought under

1. Morgan's Claims Are Expressly Preempted By Federal Law

A. Step 1: The SynchroMed II Pump is Subject to Federal Requirements

The Court finds that the first step of the express-preemption test as articulated in *Riegel* is satisfied. Morgan alleges that the device at issue is a "Medtronic SynchroMed programmable intrathecal pump" with serial number NGP379073H (Or. Pet., Dkt. 1-1, ¶ 6), and the Court takes judicial notice that the SynchroMed II Pump is a Class III, PMA-approved medical device. *See* Dkt. 5, Exhibits A, B. PMA-approved Class III devices like the SynchroMed II Pump automatically satisfy the first step of the express-preemption test. Because "[p]remarket approval … imposes [federal] 'requirements.'" *Riegel*, 552 U.S. at 322-23. Class III device manufacturers submit detailed applications for their device's approval to the FDA. Accordingly, the Court finds that the federal government has established requirements for Morgan's SynchroMed II Pump, and step one of the two-step express preemption test is satisfied.

B. Step 2: Morgan's Claims are Based on State Law that is Different From, or Additional To, Federal Law.

The Court also finds that the second step of the *Riegel* express-preemption test is satisfied. Under the MDAs that state common-law and statutory "duties underlying negligence, strict-liability, and implied-warranty claims" are considered "requirements …

Texas law); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 707 (S.D. Tex. 2014) (strict liability claim preempted whether based on design, manufacturing, or warning defects); *See also Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 657-60 (S.D. Tex. 2010) (all claims dismissed at pleading stage based on express and implied preemption); *Ilarraza v. Medtronic, Inc.*, 677 F. Supp. 2d 582 (E.D.N.Y. 2009) (dismissing claims against a SynchroMed pump at the pleading stage); *McBride v. Medtronic, Inc.*, No. 13-377, 2013 WL 3491085 (W.D. La. July 10, 2013) (same); *Cenac v. Hubbell*, No. 09-3686, 2010 WL 4174573 (E.D. La. Oct. 21, 2010) (same); *Walker v. Medtronic, Inc.*, 670 F.3d 569 (4th Cir. 2012) (affirming summary judgment on claims against a Medtronic SynchroMed pump).

with respect to devices." *Riegel*, 552 U.S. at 327. Morgan alleges that the SynchroMed II Pump was defective or unreasonably dangerous, thus satisfying the requirement that the claims "relate to safety and effectiveness." *Id.* at 322 (citing § 360k(a)). Since *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence *per se*." *See In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (citations omitted). Such claims essentially impose requirements different from or additional to those imposed by the FDA through the rigorous PMA process. Section 360k(a) leaves a narrow gap through which state-law claims may avoid express preemption if they are "premised on a violation of FDA regulations," because such claims merely "parallel"—rather than add to—federal requirements. *Riegel*, 552 U.S. at 330. Here, the Court finds that Morgan asserts no such claims. *See, e.g., Rodriguez v. Am. Med. Sys.,* Inc., 597 F. App'x 226, 228-30 (5th Cir. 2014). Each of Morgan's state-law claims would impose standards related to device safety and effectiveness that are different from, or in addition to, those required by the FDA. Therefore, the Court concludes that judgment on the pleadings is proper. *See Riegel*, 552 U.S. at 322-23.

i. Morgan's "strict liability" claims are expressly preempted.

Causes of Action 2, 3, and 4 of Morgan's Petition assert strict-liability claims in which he alleges that his injuries were caused by Medtronic placing into the stream of commerce an "unreasonably dangerous" and "defective" product. Or. Pet., Dkt. 1-1 ¶¶ 21, 28, 32. Specifically, Morgan alleges that the SynchroMed II Pump he received was

unsafe based on design defects (*id.* at ¶¶ 18-23), failure to warn (*id.* at ¶¶ 24-29), and manufacturing defects (*id.* at ¶¶ 30-34).

a. Morgan's design defect claim (Cause of Action 2) is expressly preempted.

In Cause of Action 2, Morgan alleges that Medtronic "designed…and placed the pain pump into the stream of commerce… and failed to properly and adequately test the pain pump" Or. Pet., Dkt. 1-1, ¶ 19. Morgan also alleges that "[t]he pain pump…was defective in its design…posing a serious risk [because it] would not alert anyone that there was no more pain mediation" *Id.* at ¶ 21. The Court finds this claim is expressly preempted. As explained above, the first step of the *Riegel* analysis is satisfied because the federal government has established requirements applicable to the SynchroMed II Pump. The second step is also satisfied. Morgan does not allege the design of the SynchroMed II Pump deviates from the design approved by the FDA. Therefore, Morgan's design defect claim is attempting to impose responsibilities on Medtronic that are different from, or in addition to, the federal requirements. Because both steps are met, the Court dismisses this claim as expressly preempted. *See Blankenship v. Medtronic*, Inc., 6 F. Supp. 3d 979, 989 (E.D. Mo. 2014) (finding claim expressly preempted).

Additionally, in Texas, strict-liability product defect claims are governed by Section 402A of the Restatement (Second) of Torts, which imposes liability upon those who sell unreasonably dangerous products that reach the user without substantial change in their condition and cause the user physical harm. *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 426 (Tex. 1997). A product may be "unreasonably dangerous" due to

defects in marketing, design, or manufacturing. *Id.* A design defect requires that "(1) there was a safer alternative; (2) the safer alternative would have prevented or significantly reduced the risk of injury, without substantially impairing the product's utility; and (3) the safer alternative was both technologically and economically feasible when the product left the control of the manufacturer." *Smith v. Aqua-Flo, Inc.*, 23 S.W.3d 473, 477 (Tex. App.—Houston [1st Dist.] 2000, pet. denied).

Here, Morgan's design defect claim seeks to impose different or additional requirements than those imposed by the FDA, and is therefore expressly preempted under *Riegel*. For instance, a Texas state law design defect claim requires Morgan to prove that Medtronic should have used an alternative design—a design different from that approved by the FDA through the PMA process. Such a claim "disrupts the federal scheme" for regulating Class III medical devices by requiring such devices to be "safer, but hence less effective, than the model the FDA has approved." *Riegel*, 552 U.S. at 325. Accordingly, the Court finds Cause of Action 2, design defect, expressly preempted under § 360k(a).

b. Morgan's failure to warn claim (Cause of Action 3) is expressly preempted.

Morgan alleges in Cause of Action 3 that Medtronic knew that the "pain pump would eventually run out of pain mediation" and failed to provide adequate warning. *See* Or. Pet., Dkt. 1-1 ¶ 26. The Court finds this claim is expressly preempted. Because the federal government has established requirements for the SynchroMed II Pump, the first step of *Riegel* is satisfied. The second step is also satisfied because Morgan's claim seeks to impose on Medtronic labeling or warning requirements that go beyond what federal

law requires. In other words, Morgan's claim would have to prove that Medtronic should have provided different or additional warnings from those approved by the FDA. *Riegel*, 552 U.S. at 329. Morgan's failure to warn claim is also dismissed.

c. Morgan's manufacturing claim (Cause of Action 4) is expressly preempted.

The Court finds this claim is expressly preempted. Under the first step of the express preemption analysis, the Court concludes that the federal government has established requirements applicable to the SynchroMed II Pump. In *Riegel*, the Supreme Court recognized that specifications listed in a premarket approval are federal requirements and that deviations from those specifications are considered violations of the MDA. 552 U.S. at 323, 128 S.Ct. 999. Because the SynchroMed II Pump received approval from the FDA, the federal government has established requirements that apply to it. *See Blankenship v. Medtronic, Inc.*, No. 4:13–CV–1087, 6 F.Supp.3d 979, 986–87, 2014 WL 1226491, at *4 (E.D. Mo. Mar. 25, 2014) (concluding the first step of *Riegel* is "easily answered in the affirmative"); *Beavers–Gabriel v. Medtronic, Inc.*, No. 13–686, 15 F.Supp.3d 1021, 1032, 2014 WL 1396582, at *8 (D. Haw. Apr. 10, 2014) (finding this step "appears to be plainly met"); *Dunbar v. Medtronic, Inc.*, No. 14–1529, 2014 WL 3056026, at *3 (C.D. Cal. June 25, 2014) (same).

Under the second step, the Court concludes that Morgan's manufacturing defect claim is attempting to impose responsibilities on Medtronic that are different from, or in addition to, the federal requirements. Morgan's manufacturing defect claim is preempted because it would require Morgan to prove that his SynchroMed II Pump "deviates from

the specifications or planned output" approved by the FDA, notwithstanding the fact that Morgan has not alleged how his SynchroMed II Pump deviated from the FDA pre-market approved plans. *Riegel*, 552 U.S. at 328. Morgan does not identify any specific manufacturing requirement imposed by the FDA that Morgan allegedly violated. Therefore, Morgan's claim would require the SynchroMed II Pump to be manufactured differently than the FDA authorized. As such, this claim is expressly preempted.

Finally, as discussed above, both the United States Supreme Court and Texas courts acknowledge that strict-liability claims brought under state law impose requirements that are "different from, or in addition to," those imposed by the FDA through the PMA process. 21 U.S.C. § 360k(a)(1). Therefore, the Court finds that Medtronic is entitled to judgment in its favor on Morgan's strict-liability claims based on express preemption.

ii. Morgan's negligence claim is expressly preempted.

Morgan also asserts a common-law negligence claim against Medtronic. In Cause of Action 1, Morgan contends that Medtronic acted negligently by "fail[ing] to exercise reasonable care in the design, manufacture, testing, marketing, distribution, testing and placement of the pump." Or. Pet., Dkt. 1-1 ¶ 15. Morgan alleges that Medtronic either failed to design the pump to notify the patient when there was no more pain medication or provided Morgan with a faulty pump. *Id.* Medtronic "continued to market the pain pump as safe" despite these purported failures. *Id.* at ¶ 16. Morgan claims that Medtronic "failed to perform adequate testing and evaluations of the pump prior to placing the pump into the stream of commerce." *Id.* at ¶ 14.

The Court reiterates that any cause of action that requires proof of a safer alternative design imposes requirements "different from, or in addition to," those imposed by the FDA through the PMA process. 21 U.S.C. § 360k(a)(1). Morgan's claim that Medtronic acted negligently in failing to provide a product with some other type of alarm (Or. Pet., Dkt. 1-1, ¶ 15) asserts that Medtronic should have taken another approach in designing and manufacturing the SynchroMed II Pump. Therefore, Morgan's negligence claim is expressly preempted. *Riegel*, 552 U.S. at 324-25.

iii. Morgan's warranty claims are expressly preempted.

Morgan asserts claims for breach of express warranty (Cause of Action 5) and breach of implied warranties (Causes of Action 6 and 7) in which he argues the SynchroMed II Pump is not safe and effective. Morgan alleges that Medtronic "expressly warranted that [the SynchroMed II Pump] was safe for use in the body of its users," but "did not conform to these express representations thereby giving rise to Plaintiff's injuries and damages." Or. Pet., Dkt. 1-1, ¶¶ 37-38. On his claim for breach of the implied warranty of merchantability, Morgan similarly asserts that Medtronic "impliedly warranted the pain pump to be of merchantable quality and safe for its intended use and that Plaintiff relied on that warranty, but in reality, the device's purported defects rendered it unreasonably dangerous and unfit for its intended use. *Id.* at ¶¶ 42-44. Additionally, Morgan alleges that despite Medtronic's alleged assurances, the SynchroMed II Pump "was not fit for its particular purpose, as it was unreasonably dangerous as described above." *Id.* at ¶ 50.

The Court finds all of Morgan's state law breach of warranty claims that purport to impose liability on Medtronic despite their compliance with the applicable FDA design and manufacturing specifications, as approved by the FDA during the PMA process, seek to impose different or additional state duties and are expressly preempted. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 769 (5th Cir. 2011); *see also Bass v. Stryker Corp.*, 669 F.3d 501, 517 (5th Cir. 2012). The Fifth Circuit had "held such traditional state products liability claims to be expressly preempted even prior to *Riegel's* confirmation that these types of claims may not be maintained under § 360k." *Id.* (citing *Gomez v. St. Jude Medical Daig. Div., Inc.*, 442 F.3d 919, 930–31 (5th Cir. 2006); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 575 (5th Cir. 2001).)

Because all of the claims are preempted under 21 U.S.C. § 360k, Morgan fails to state a claim upon which relief can be granted, and Medtronic's 12(c) Motion is therefore granted. *See Hughes*, 631 F.3d at 768 (citing *Riegel*, 552 U.S. at 322); *see also Timberlake v. Synthes Spine, Inc.*, No. CIV.A. V-08-4, 2011 WL 711075, at *7 (S.D. Tex. Feb. 18, 2011) (plaintiff's claims for, inter alia, strict liability , breach of express warranty, and negligence based on alleged failure of spinal disc preempted by MDA); *Lewkut v. Stryker Corp.*, 724 F.Supp.2d 648, 657 (S.D. Tex. 2010) (dismissing on 12(b)(6) plaintiff's for strict liability, negligence, and deceptive trade practices) (citing *Worthy v. Collagen Corporation*, 967 S.W.2d 360, 376–377 (Tex. 1998)); *Funk v. Stryker Corp.*, 673 F.Supp.2d 522, 532 (S.D. Tex. 2009) (dismissing on 12(b)(6) plaintiff's strict liability, negligence, and Texas Deceptive Trade Practices Act claims based on alleged injury from a defective hip implant as preempted under the MDA);

Miller v. DePuy Spine, Inc., 638 F.Supp.2d 1226, 1231 (D. Nev. 2009) (dismissing on summary judgment plaintiff's product liability, negligence, and breach of warranties claims against DePuy Spine, Inc. based on allegedly defective Charite disc as preempted under the MDA).

In conclusion, Morgan's negligence, strict-liability, and warranty claims are barred by express preemption under § 360k(a) because they seek to impose different or additional requirements related to safety and effectiveness than those imposed by federal law through the PMA process. Further, even if Morgan attempted to connect his clams to specific federal requirements, the claims would then be impliedly preempted under § 337(a). Although embedded in state-law terms, any such claims would "exist solely by virtue of [federal law]." *Buckman*, 531 U.S. at 353. Because only the federal government can enforce the FDCA and its regulations, any claims asserting violations of federal law would conflict with the FDA's own extensive regulatory regime. Accordingly, this Court finds that, to the extent Morgan's claims are not expressly preempted under 21 U.S.C. § 360k(a), they are impliedly preempted under 21 U.S.C. § 337(a).

C. Pre-Suit Notice

The Court also dismisses Morgan's breach of warranty claims because he did not provide Medtronic with pre-suit notice of the alleged breach, as required by Texas law. To bring a breach of warranty claim, a plaintiff "must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from remedy." TEX. BUS. & COM. CODE § 2.607(c)(1). Courts in Texas consistently hold that failure to provide pre-suit notice is fatal to a plaintiff's warranty claim. *See, e.g., U.S.*

Tire-Tech, Inc. v. Boeran, B.V., 110 S.W.3d 194, 201 (Tex. App.—Houston [1st Dist.] 2003, pet. denied) (plaintiff's breach of warranty claims fail because plaintiff provided no notice to manufacturer); *see also McKay v. Novartis Pharm. Corp.*, 934 F. Supp. 2d 898, 913 (W.D. Tex. 2013) *aff'd sub nom. McKay v. Novartis Pharm. Corp.*, 751 F.3d 694 (5th Cir. 2014). Here, Morgan does not allege in his Original Petition that he complied with the pre-suit notice requirements. Instead, Morgan argues that because this case was originally filed in state court, he was "only required to give [Medtronic] notice of his claim." Dkt. 8, ¶ 10. Because Morgan did not notify Medtronic "within a reasonable time" of his belief that Medtronic breached any alleged warranty (TEX. BUS. & COM. CODE §2.607(c)(1)), his breach-of-warranty claims are dismissed with prejudice, outside the issue of preemption.

CONCLUSION AND ORDER

After careful consideration of the pleadings, the 12(c) Motion, the record and evidence in this case, and the arguments of the parties, the Court finds that the motion should be granted in full for the reasons set forth above. All claims by Morgan against Medtronic in the above-captioned case will be **DISMISSED WITH PREJUDICE**. Accordingly, Defendant's Motion for Judgment on the Pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure (Dkt. 5) is, hereby, **GRANTED**.

IT IS SO ORDERED.

Final judgment will be entered separately.

SIGNED AT GALVESTON, TEXAS, on March 22 2016.

GEORGE C. HANKS, JR.
UNITED STATES DISTRICT JUDGE